SUBCHAPTER 47B - CANCER REGISTRY

SECTION .0100 – CANCER REGISTRY

10A NCAC 47B .0101 GENERAL

(a) The purpose of the central cancer registry is to receive and to compile, tabulate, and preserve statistical, clinical, and other reports and records relating to the incidence, treatment and cure of cancer, and to provide assistance and consultation for public health work. The statistical reports and records, and the assistance rendered to health care facilities, health planning agencies and research facilities are intended to improve cancer treatment, extend the life of the cancer patient, identify high risk groups or areas of the state and attempt to lower the morbidity and mortality of cancer in North Carolina.

(b) The central cancer registry is administered by State Center for Health Statistics, Division of Public Health, North Carolina Department of Health and Human Services, 1908 Mail Service Center, Raleigh, North Carolina 27699-1908.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
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10A NCAC 47B .0102 DEFINITIONS

The following definitions shall apply throughout this Section:

(1) "Abstract" refers to a document or documents, including electronic documents and files, containing information drawn from a cancer patient's medical record.

(2) "Cancer registrar" is a registrar who abstracts information from the medical records of cancer patients.

(3) "Death match" refers to the procedure of comparing registry cases with death certificate information, for confirmation of the reported death of any cancer patient, to determine if the cancer constituted the cause of death, and for identification of cases missed in routine reporting procedures.

(4) "Definitive treatment" refers to all methods of treatment intended to modify or control the cancer including no treatment, palliative care, and follow-up care.

(5) "Follow-up information" is information on the post-treatment status of a cancer patient whose abstract was submitted to the registry previously.

(6) "Identifying information" is any portion of any abstract that might reveal the personal identity of a cancer patient.

(7) "Morphologic information" refers to pathology, cytology, tumor markers, or laboratory tests that identify cell types of malignant neoplasms.

(8) "Palliative treatment" refers to treatment that is not intended to effect a cure, but the treatment procedure is expected to improve "quality of life" by temporarily relieving distressing symptoms.

(9) "Participating facility" is a health care facility that submits abstracts to the registry.

(10) "Pathology report" is the written report generated by a pathologist, stating the diagnostic interpretation of tissue samples or cellular material examined by the pathologist.

(11) "Personnel" means persons who are employees of the Department of Health and Human Services, or who are persons who provide services to the central cancer registry through a written contract.

(12) "Positive pathology report" is a pathology report confirming the presence of cancer.

(13) "Registrar" is an employee of a health care facility who prepares abstracts of medical records.

(14) "Registry" is the central cancer registry. The registry is administratively assigned to the State Center for Health Statistics, Department of Health and Human Services.

(15) "Statistical report" refers to a report generated by the registry for informational or educational purposes. A statistical report contains aggregated data and does not contain identifying information.

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10A NCAC 47B .0103 CONFIDENTIALITY

(a) The clinical records of individual patients submitted to the registry shall be confidential and shall not be public records open to inspection. Only personnel authorized by the director of the State Center for Health Statistics and other individuals authorized by the director of the State Center for Health Statistics or his/her designee pursuant to Paragraph (c) of this Rule shall have access to the records.

(b) The information contained in the clinical records of individual patients submitted to the registry may be transferred to computer-compatible means of data entry. Only personnel authorized by the director of the State Center for Health Statistics to use computers, terminals, programs, data files, and other computer hardware or software involved in maintaining patient information shall have access to them.

(c) Clinical information in possession of the registry may be disclosed in the following circumstances when authorized by the director of the State Center for Health Statistics or his/her designee:

(1) A patient shall have access to review or obtain copies of his/her records;
(2) Information may be disclosed in response to a valid court order;
(3) Information may be disclosed as provided in Rule .0106 of this Section;
(4) Information contained in death certificates on file with the division (but not actual copies of death certificates) may be released to a participating facility when the facility requests a death match for confirmation of the reported or suspected deaths of cancer patients treated at that facility. Death match information released by the registry shall include only that information contained in the death certificates.

(d) The State Center for Health Statistics may release statistical information and data based on client information so long as no information identifying individual patients is released.

(e) Photocopying or other reproduction of any clinical records or reports containing identifying information, except as may be required in the conduct of the official business of the registry, is prohibited.

(f) Any legible documents other than the original abstracts, such as computer printouts or photocopies of any documents containing identifying information, shall also be considered confidential material while in active use, and shall be destroyed immediately upon termination of their use by the registry.

(g) Original copies of reports and abstracts, and follow-up information received thereunto, shall be retained for 5 years by the registry.

(h) The director of the State Center for Health Statistics shall make known to all individuals with access to patient information submitted to the registry the privileged and confidential nature of such information.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
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10A NCAC 47B .0104 REPORTING OF CANCER

(a) Health care facilities and providers shall submit a complete abstract for each cancer case that is screened, diagnosed, treated, or followed by its staff and that was initially diagnosed with cancer subsequent to May 7, 1999. A complete abstract is defined as one that adheres to the standards and definitions of the North American Association of Central Cancer Registries (NAACCR), the World Health Organization (WHO), the American College of Surgeons Commission on Cancer (COC), and the National Cancer Institute Surveillance, Epidemiology, and End Results Program (SEER). These standards and definitions are delineated in the following publications: the NAACCR *Standards for Cancer Registries,* the WHO *International Classification of Diseases for Oncology;* the COC *Standards of the Commission on Cancer, Volume II, Registry Operations and Data Standards (ROADS);* and the SEER Coding Manuals. Subsequent amendments and editions of these publications are included. NAACCR

documents are free of charge and may be obtained from the North American Association of Central Cancer Registries, 2121 West White Oaks Drive, Springfield, Illinois 62704. The *International Classification of Diseases for Oncology* may be purchased for twenty-seven dollars ($27.00) from WHO Publications Center USA, 49 Sheridan Avenue, New York, NY 12210. The *ROADS* publication may be purchased for twenty dollars ($20.00) from ACS Publications Fulfillment Section, Box 92425, Chicago, IL 60675-2425. SEER publications are free of charge and may be obtained from the National Cancer Institute, Publications Ordering Service, P.O. Box 24128, Baltimore, MD 21227.

(b) A health care provider or facility may delegate the tasks of reporting cancer cases to office or hospital staff, but the provider or facility shall not delegate the legal responsibility for the reporting of cancer to others.

(c) A report of cancer shall be submitted to the registry by health care facilities and providers by one of the following methods:

(1) by submission of an electronic file containing the information required in Paragraph (a) of this Rule;

(2) for pathology laboratories, by submission of a positive electronic pathology report containing the information required in Paragraph (a) of this Rule; or

(3) facilities or providers that have fewer than 30 reportable cases per year may submit photocopies of the medical record sufficient to complete a full abstract of the case.

(d) The following documents shall not constitute a report of cancer:

(1) a death certificate; and

(2) a request for authorization submitted to the Cancer program requesting third party reimbursement for treatment of cancer, although a positive pathology report is required by 10 NCAC 8A .0408(f).

(e) Reports shall be forwarded to the following address: Central Cancer Registry, State Center for Health Statistics, 1908 Mail Service Center, Raleigh, North Carolina 27699-1908.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
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10A NCAC 47B .0105 COOPERATION OF THE CENTRAL CANCER REGISTRY WITH HEALTH FACILITIES

(a) Any health care facility that is staffed and equipped for the diagnosis, treatment or follow-up care of cancer patients may participate with the registry in the exchange of information regarding the referral, treatment, maintenance or cure of cancer.

(b) The registry shall cooperate and consult with participating health care facilities and providers to the end that cancer registries in such facilities may provide the most accurate data available and may otherwise operate in the best interest of the cancer patients being treated therein. The registry will provide:

(1) Quality control reports to assure that computerized data utilized for statistical information and data compilation are correct;

(2) The most accurate and effective treatment, survival and comparative information available;

(3) Educational information available from registry, morbidity and mortality statistics upon request of a professional staff;

(4) Assistance to health care facilities by providing appropriate data and consultation to help the facilities meet the requirements for accreditation as a cancer treatment center, and to assist in the maintenance of such accreditation;

(5) Confirmation of the reported or presumed deaths (including such causes of deaths) of cancer patients to assist health care facilities to more accurately assess patient survival and to conduct more efficient long-term follow-up of cancer patients;

(6) Other information for the purpose of follow-up of a patient. This information is limited to the name of another facility or physician providing services to the patient, the date of last contact with the patient, and the vital status.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*

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10A NCAC 47B .0106 RELEASE OF CENTRAL CANCER REGISTRY DATA FOR RESEARCH

(a) The registry may release statistical data to any person or agency for the following purposes:

(1) medical research or education;
(2) epidemiological studies;
(3) health education;
(4) health planning or administration;
(5) required statistical reports; and
(6) other statistical reports by written request for research, information or education.

(b) A researcher may request the release of medical records from the registry by the submission of a written research proposal. This request must adhere to the requirements pertaining to release of medical records by the State Center for Health Statistics as defined by 10A NCAC 47A .0102.

(c) The medical records or reports of the individual patients may be disclosed to research staff for the purpose of medical research, provided that the registry has determined that:

(1) disclosure of this information is deemed necessary to accomplish the purposes of the research;
(2) the research warrants the risk to individual patients of the potential disclosure of their medical records; and
(3) adequate safeguards to protect the medical records or identifying information are established or maintained.

(d) The registry shall provide regular reports of research activity and data released to the cancer committee of the North Carolina Medical Society. Where there exists the potential for direct patient contact, the registry shall consult with the chairman of the Committee on Cancer of the North Carolina Medical Society before determining to release information for research as provided in Paragraphs (b) and(c) of this Rule. The registry shall forward the research proposal to the chairman for review. The chairman may forward the proposal to any or all members of the committee for comment.

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10A NCAC 47B .0107 RESERVED FOR FUTURE CODIFICATION

10A NCAC 47B .0108 ASSISTANCE AND CONSULTATION FOR PUBLIC HEALTH WORK

(a) The registry shall provide assistance and consultation for public health work.

(b) The registry shall accept requests for assistance and consultation for any agency, facility or organization actively engaged in the effort to reduce the incidence of cancer, whether through direct service to or the education of cancer patients and their families, the public, or the health care professions.

(c) The registry may accept requests from students requesting assistance with research projects in accordance with the provisions of Rule .0106 of this Subchapter and the availability of staff time and resources.

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10A NCAC 47B .0109 FAILURE TO REPORT

(a) The registry shall monitor the reporting of health care facilities and providers on a quarterly basis. If a health care facility or provider has failed to report at least 90 percent of its cases within six months of diagnosis, the registry shall notify the facility or provider in writing of that fact within 30 days and the facility or provider shall be given another 30 days, or up to 60 days for good cause shown, to fulfill its reporting requirement.

(b) If a facility or provider is out of compliance for two consecutive quarters and is not demonstrating progress toward becoming compliant, then the State Health Director shall direct the registry to collect the data and shall direct the facility or provider to reimburse the registry for all actual costs expended in order to obtain the data up to one hundred dollars ($100.00) per case abstracted. The amount of the reimbursement shall include both travel expenses and the full cost of personnel time.

(c) Facilities or providers may request the director of the registry for abstracting assistance at no cost to them. The decision as to what assistance will be provided shall be based on the following:

(1) Size of the facility;
(2) Consistency of non-compliance;
(3) Staffing of the registry;
(4) Duration of needed assistance. The registry shall not provide long term abstracting assistance to any facility that has greater than 100 cases per year;
(5) The potential for compromising the registry's data quality; and
(6) Plans of the facility to reach compliance.

History Note: *Authority G.S. 130A-205; 130A-208 through 130A-213;*
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